

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 15 JUL 2005

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Applicant's or agent's file reference 564462004040	FOR FURTHER ACTION		See Form PCT/IPEA/416																
International application No. PCT/US04/08541	International filing date (day/month/year) 18 March 2004 (18.03.2004)	Priority date (day/month/year) 20 March 2003 (20.03.2003)																	
International Patent Classification (IPC) or national classification and IPC IPC(7): C12P 21/06; C12N 9/00, 9/24, 1/20, 15/00; C11D 3/50; C07K 16/00; C07H 21/04 and US Cl.: 435/69.1, 183, 200, 252.3, 287.2, 320.1; 510/114, 392; 530/387.1, 830; 536/23.2; 712/1, 90																			
Applicant DIVERSA CORPORATION																			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>2</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table style="margin-left: 20px; width: 80%;"> <tr><td><input checked="" type="checkbox"/> Box No. I</td><td>Basis of the report</td></tr> <tr><td><input type="checkbox"/> Box No. II</td><td>Priority</td></tr> <tr><td><input checked="" type="checkbox"/> Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr> <tr><td><input checked="" type="checkbox"/> Box No. IV</td><td>Lack of unity of invention</td></tr> <tr><td><input checked="" type="checkbox"/> Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</td></tr> <tr><td><input type="checkbox"/> Box No. VI</td><td>Certain documents cited</td></tr> <tr><td><input type="checkbox"/> Box No. VII</td><td>Certain defects in the international application</td></tr> <tr><td><input type="checkbox"/> Box No. VIII</td><td>Certain observations on the international application</td></tr> </table>				<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input type="checkbox"/> Box No. VIII	Certain observations on the international application
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Date of submission of the demand 18 October 2004 (18.10.2004)		Date of completion of this report 03 May 2005 (03.05.2005)																	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer <i>Manjunath N. Rao, Ph.D.</i> Telephone No. 571-272-1600																	

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/08541

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
 - ☐ the international application as originally filed/furnished
 - ☒ the description:
 - pages 1-131 as originally filed/furnished
 - pages* NONE received by this Authority on _____
 - pages* NONE received by this Authority on _____
 - ☒ the claims:
 - pages 132-170 as originally filed/furnished
 - pages* NONE as amended (together with any statement) under Article 19
 - pages* NONE received by this Authority on _____
 - pages* NONE received by this Authority on _____
 - ☒ the drawings:
 - pages 1-8 as originally filed/furnished
 - pages* NONE received by this Authority on _____
 - pages* NONE received by this Authority on _____
 - ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages _____
 - ☐ the claims, Nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to the sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages _____
 - ☐ the claims, Nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. Claim 23 (depends on itself)

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 23 are so unclear that no meaningful opinion could be formed (*specify*):

Claim 23 is not further limiting because it depends from itself.

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for said claims Nos. _____

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

- | | | |
|----------------------------|--------------------------|-----------------------------------|
| the written form | <input type="checkbox"/> | has not been furnished |
| | <input type="checkbox"/> | does not comply with the standard |
| the computer readable form | <input type="checkbox"/> | has not been furnished |
| | <input type="checkbox"/> | does not comply with the standard |

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- ☐ See Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

- ☐ complied with.
- ☒ not complied with for the following reasons:

See the lack of unity section of the International Search Report(Form PCT/ISA/210)

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☐ all parts
- ☒ the parts relating to claims Nos. 1-22, 24-218 and SEQ ID NO:1 and 2 only

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

Inventive Step (IS)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

Industrial Applicability (IA)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

2. Citations and Explanations (Rule 70.7)

Please See Continuation Sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion was established on the basis of:

a. type of material



a sequence listing



table(s) related to the sequence listing

b. format of material



in written format



in computer readable form

c. time of filing/furnishing



contained in the international application as filed



filed together with the international application in computer readable form



furnished subsequently to this Authority for the purposes of search and/or examination



received by this Authority as an amendment* on _____

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 3-4, 16-22, 40-46,
The opinion as to Novelty was negative (No) with respect to claims 1-2, 5-15, 24-39, 47-48, 52-82, 99, 103-128, 207-208
The opinion as to Inventive Step was positive (Yes) with respect to claims 3-4, 16-22, 40-46,
The opinion as to Inventive Step was negative (NO) with respect to claims 1-2, 5-15, 24-39, 47-218
The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-22, 24-218
The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

Claims 1-2, 5-15, 24-39, 47-48 lack novelty under PCT Article 33(2) as being anticipated by deSILVA et al. Claims 1-2, 5-15, 24-39, 47-48 are drawn to a polynucleotide comprising a polynucleotide having at least 80% sequence identity to SEQ ID NO:1 over a region of at least 100 nucleotides or full length of SEQ ID NO:1, wherein said polynucleotide encodes a α -glucosidase enzyme with characteristics as claimed in claims 5-15, vectors and host cells comprising the same as claimed in claims 24-39 and 47-48. deSILVA et al. disclose such a polynucleotide wherein it has at least an 80% sequence identity over 100 nucleotides and wherein said polynucleotide encodes an α -glucosidase, vectors and host cells comprising the same thereby anticipating claims 1-2, 5-15, 24-39, 47-48.

Claims 49-51, 129-153, 193-206 lack an inventive step under PCT Article 33(3) as being obvious over deSILVA et al. and the common knowledge in the art of molecular biology. Claims 49-51, 129-153, 193-206 to method of making double stranded iRNA, a method of generating variants of the nucleic acid disclosed by deSILVA et al. and an expression cassette comprising said polynucleotide. With the polynucleotide provided by deSILVA et al. it would have been obvious to those skilled in the art to make double stranded iRNA, generate variants of the nucleic acid disclosed by deSilva et al. and an expression cassette comprising said polynucleotide. One of ordinary skill in the art would have been motivated to do so in order to control the expression of said polynucleotide. One of ordinary skill in the art would have a reasonable expectation of success since deSILVA et al. provides the polynucleotide and the art provides method to manipulate the same.

Claims 52-82, 99, 103-128, 207-208 lack novelty under PCT Article 33(2) as being anticipated by LEGIN et al. Claims 52-82, 99, 103-128, 207-208 are drawn to an α -glucosidase having characteristics such as thermostability and wherein it comprises an amino acid that is SEQ ID NO:2. LEGIN et al. discloses a thermostable α -glucosidase having a half life of 1 to 5 hours at 95 degree C. The reference does not disclose the amino acid sequence of the same. However, in view of the identical activity, the Authorized Officer takes the position that the reference enzyme inherently has the same amino acid sequence as that of SEQ ID NO:2 and all other characteristics. Therefore LEGIN et al. anticipates claims 52-82, 99, 103-128, 207-208 as written.

Claims 72-73, 83-98, 100-102, 154-191, 209-218 lack an inventive step under PCT Article 33(3) as being obvious over LEGIN et al. in view of KELLY et al. Claims 72-73, 83-98, 100-102, 154-191, 209-218 are to various method of using the α -glucosidase enzyme with SEQ ID NO:2. However, with the teachings of LEGIN et al. which discloses a thermostable glucosidase in combination with the

Supplemental Box

teachings of KELLY et al. which teaches various methods and uses for a thermostable glucosidase starting from its use in a detergent composition to the liberation of glucose from starch and other polysaccharides, it would have been obvious to those skilled in the art to develop all the claimed uses for the enzyme taught by Legin et al. One of ordinary skill in the art would have been motivated to do from the teachings of KELLY et al. One of ordinary skill in the art would have had a reasonable expectation of success since LEGIN et al. provide the enzyme and KELLY et al. teaches the multiple uses for the enzyme. Therefore, the claims 72-73, 83-98, 100-102, 154-191, 209-218 would have been prima facie obvious to those skilled in the art.

Claims 3-4, 16-22, 40-46 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a polynucleotide with SEQ ID NO:1 as well as vectors and host comprising the same.

Claims 1-22, 24-218 (as applied to SEQ ID NO:1 and 2 only) meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.